REMARKS

Claims 8-9 are canceled without prejudice or disclaimer. Applicants reserve the right to pursue the canceled claims in one or more continuing applications.

Claims 10 and 11 have been amended to replace the term "gene" with "nucleic acid." New dependent claims 28-45 have been added. The amended and new claims are supported throughout the application, e.g., at page 13, lines 5-6 and 14-15; and page 16, lines 1-2. Upon entry of this amendment, claims 1-7 and 10-37 will be pending and claims 10, 11 and 28-45 will be under examination.

Rejections Under 35 U.S.C. §112, First Paragraph

Enablement

Claims 8-11 are rejected because, according to the Examiner,

> the specification, while being enabling for a method for screening for a nucleic acid which encodes a polypeptide that converts an inactive form of vitamin D3 into an active form, does not reasonably provide enablement for a method for screening for a gene encoding a polypeptide that converts an inactive form of vitamin D3 to an active form, or a method for screening for a gene encoding an [*sic*, a] polypeptide that converts a ligand precursor into a ligand. (Office action, paragraph bridging pages 2-3.)

Claims 8 and 9 are canceled and claims 10 and 11 have been amended to recite screening a test "nucleic acid" that encodes a polypeptide rather than a test "gene" that encodes a polypeptide. This amendment is implicitly supported throughout the entire application. The present claims are thus commensurate with the Examiner's acknowledged scope of enablement. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Written Description

Claims 8-11 are rejected as "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that that the inventor(s), at the time the application was filed, had possession of the claimed invention." The Examiner states:

> The specification discloses methods for screening for a nucleic acid which encodes a polypeptide that converts an inactive form of vitamin D3 into an active form wherein the nucleic acid is from human or mouse (i.e., SEQ ID NO: 1, 2 see page 16). However, detailed information regarding the structural and functional requirements of the gene encoding the polypeptide, as well as structural and functional requirements of the encoded polypeptide itself are lacking. (Office action, page 5.)

This rejection has been addressed, in part, by canceling claims 8 and 9 and amending claims 10 and 11 to recite screening a "test nucleic acid" that encodes a polypeptide rather than a "test gene" that encodes a polypeptide. However, the Examiner's implication that there is written description for a test nucleic acid from only human and mouse is respectfully traversed. For at least the following reasons, a skilled artisan would recognize that Applicants were in possession of the full scope of "test nucleic acids" to be screened in the claimed methods.

The present claims are directed to methods of screening. By definition, agents to be tested in a method of screening (in this case, test nucleic acids that encode a polypeptide) are not limited to one particular structure or one particular source. Indeed, screening assays are routinely claimed in terms of specific "test compounds" where no particular compounds are disclosed in the specification, because the invention lies in the steps of the method, not in the identity of the compounds that can be run through the screening assay. Here, even more than the usual detail is given in the claims, in that the compound to be tested must be a nucleic acid encoding a polypeptide.

A skilled artisan would understand that a "test nucleic acid encoding a polypeptide" describes, e.g., nucleic acids found in conventional, art-recognized, routinely available DNA libraries, such as cDNA or genomic libraries, from various sources. See, e.g., the specification at page 13, lines 21-22, which provides: "Genes are screened from cells or cDNA libraries prepared from mRNA isolated from tissues or the like, which are expected to express an objective gene." As stated in the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. §112, paragraph 1 "Written Description" Requirement (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday, January 5, 2001) (hereinafter "the Guidelines") "[t]he absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. § 112, paragraph 1, for lack of adequate written description." Prior to the priority

date, libraries of test nucleic acids were well-established and readily available from numerous sources, including human, mouse, bovine, cat, chicken, fruit fly, monkey, gorilla, orangutan, gibbon, rabbit, rat, and yeast (see ATCC Catalogue of Recombinant DNA Materials, 3rd edition, 1993, page 9, copy enclosed). Indeed, the *raison d'etre* of such DNA libraries is to provide test nucleic acids from numerous sources to be screened for various purposes, and this much would be understood by a skilled artisan faced with the term "test nucleic acid encoding a polypeptide". Given the ready availability of test nucleic acids from numerous species, Applicants' disclosure of mouse and human test nucleic acids is fairly representative of the full scope of the term. In fact, it would not have been necessary to name any species of animal in order to establish that Applicants were in possession of the full scope of the invention. Accordingly, the written description requirement is satisfied.

In light of the foregoing, Applicants respectfully request that the rejection be withdrawn.

Enclosed is a Petition for Extension of Time along with the required fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: March 23, 2004

for Janis K. Fraser, Ph.D., J.D.
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ATCC

Catalogue of Recombinant DNA Materials

3rd edition, 1993

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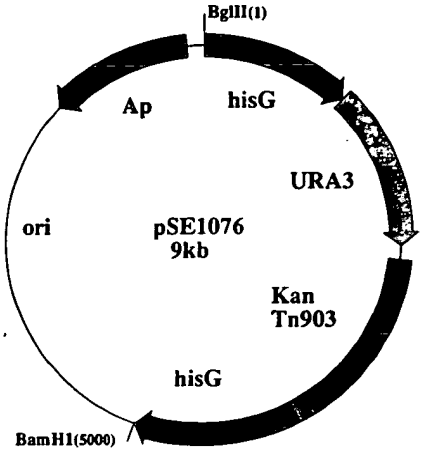

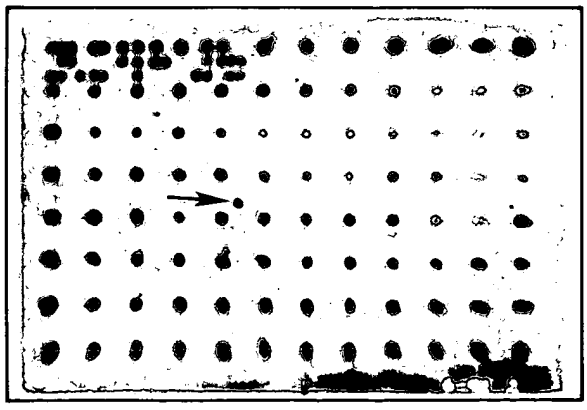

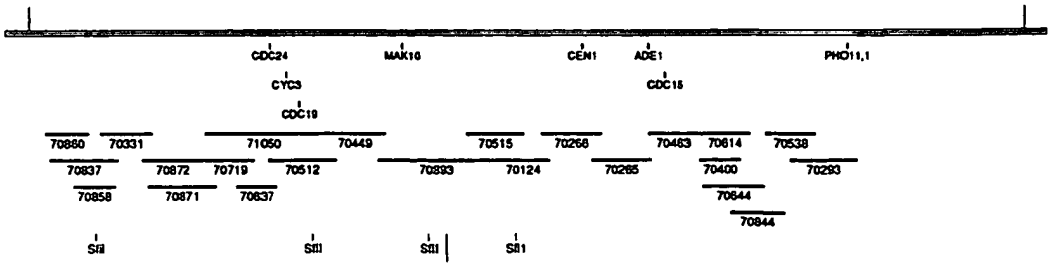

American

ATCC Catalogue of Recombinant DNA Materials*

Third edition, 1993

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Editors:

D.R. Maglott, Ph.D.
W.C. Nierman, Ph.D.

*Except for human materials found in the companion volume, ATCC/NIH Repository Catalogue of Human and Mouse DNA Probes and Libraries.

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cDNA AND GENOMIC LIBRARIES

Name	I[2]	Library	Vector	Rest Enzyme	D[1]	Insert Range kb	Depositor	ATCC® No.	Price Code	Reference(s)
Alteromonas haloplanktis	g		pBR322	*Sau*3A1	P	7-28 kb, 8.2 av	MACLEOD	37436	E	1812, 1813
Bacillus subtilis	g		Charon 4A	*Eco*RI	P	15 kb average	HOCH	37356	E	1810
bovine lymphocyte, Con A/PMA-stimulated, 15 hr	c		λgt11			> 0.2 kb	REEVES	37483	E	1777, 1816
cat placenta	g		λJ1	*Mbo*I	P	17-22 kb	ROY-BURMAN	77094	E	3815-3817
chicken erythrocyte	g		λ EMBL3	*Sau*3A1	P	10-20 kb	HEUMANN	37501	E	1964
Drosophila melanogaster	g		Charon 4A			16 kb average	MANIATIS	37332	E	1806
Escherichia coli	g		λSE6	*Sau*3A1	P	12-17 kb	ELLEDGE, WALKER	37386	E	1807
Formosa monkey thymus	g	LI013	Charon 4A	*Eco*RI	P	10-20 kb	SAKAKI	*57764	E	485
gorilla lymph node	g	LI010	Charon 4A	*Eco*RI	P	10-20 kb	SAKAKI	*57761	E	485
human	g	DK	Charon 4A	*Eco*RI	P	16-22 kb	BANK	37385	E	40, 2731
human basal ganglia, 1-day-old infant, < 6 hr autolysis	c	LMG3	λgt11			> 0.8-1.0 kb	LAZZARINI	37433	E	116
human brain stem, 1-day-old infant, < 6 hr autolysis	c	LMG2	λgt11			> 0.8-1.0 kb	LAZZARINI	37432	E	116
human fetal liver	g		Charon 4A	*Hae*III/*Alu*I	P	15-20 kb	MANIATIS	37333	E	610
human leukocyte, 68-year-old female, Black, with NIDDM	g		λMG14	*Mbo*I	P	15-20 kb	ROTWEIN	37458	E	201, 1820
human lymph nodes	g	LI014	Charon 4A	*Hae*III/*Alu*I	P	15-20 kb	SAKAKI	*57760	E	
human spinal cord, 1-day-old infant	c	LMG4	λgt11			> 0.8-1.0 kb	LAZZARINI	37434	E	116
human SSPE cerebellum, 7-year-old, < 6 hr autolysis	c	LMG5	λgt11			> 0.8-1.0 kb	LAZZARINI	37435	E	116
human thymus, female, Caucasian, 23-year-old	c	normalized thymus cDNA	λgt10	*Eco*RI	C	0.4-2 kb	PATANJALI, WEISSMAN	77081	E	3779
human tonsil	c	λS2T	λgt11			2-7 kb	KLICKSTEIN	37546	E	284, 432, 704
human tonsil	c	λT	λgt11			1.2 kb average	KLICKSTEIN	37545	E	34, 705, 749
mouse embryo	g		Charon 28	*Mbo*I	P	16-20 kb	LEDER	37484	E	
mouse telencephalon, embryonic day 15	c	E171	E61	*Not*I	C	0.3-10 kb	RUBENSTEIN	77310	E	4479, 4830
mouse whole brain, 18-day-old	c	LMG	λgt11			> 0.8-1.0 kb	LAZZARINI	37431	E	
Onchocerca volvulus	c		λgt11				DONELSON	37509	E	2351
Onchocerca volvulus	c		λZAPII			0.2-1.8 kb	DONELSON	37711	E	
orangutan lymphocyte	g	LI011	Charon 4A	*Eco*RI	P	10-20 kb	SAKAKI	*57762	E	485
Pasteurella haemolytica	g	λEMBL4::PhBam	λEMBL4	*Bam*H1	C	9-25 kb	†Patent deposit	40324	E	3208
Pasteurella haemolytica	g	λEMBL4::PhSau	λ EMBL4	*Sau*3A1	P	9-24 kb	†Patent deposit	40325	E	3208
rabbit liver	g		Charon 4A	*Hae*III and *Alu*I	P	17 kb average	HARDISON	37376	E	1806
rat brain, 2-weeks-old	c		λgt11			0.5 kb average	GOLDIN	37477	E	1817
rat brain, 2-weeks-old	c		λgt11			0.3 kb average	GOLDIN	37476	E	1818
rat brain, 12-weeks-old, cytoplasmic poly(A)+ RNA	c		λgt10			> 0.2-3 kb	BROSIUS	37478	E	1814
Saccharomyces cerevisiae	g	CEN BANK	YCp50	*Sau*3A1	P	10-20 kb	ROSE	37415	E	1821, 2119
Saccharomyces cerevisiae	g		λEMBL3A	*Sau*3A1	P	12-15 kb	ELLEDGE	77257	E	
Saccharomyces cerevisiae	g		p366	*Sau*3A1	P	9-12 kb	HIETER	77162	E	
Saccharomyces cerevisiae	g		pRS200	*Sau*3A1	P	8-10 kb	HIETER	77164	E	
Saccharomyces cerevisiae	g		λYES-R		S	4-8 kb	ELLEDGE	77256	E	4639
Saccharomyces cerevisiae	g		YEp13	*Sau*3A1	P	5-20 kb	REED	37323	E	1809
Saccharomyces cerevisiae	g	pURSC1	YRp7	*Sau*3A1	P	5-20 kb	REED	37324	E	1809
Saccharomyces cerevisiae	g	pURSC2	pUR18	*Sau*3A1	P	3-10 kb	BARBET, CARR	77295	E	4594
white-handed gibbon lymphocyte	g	LI012	pUR18	*Sau*3A1	P	1.5-4.0 kb	BARBET, CARR	77296	E	4594
			Charon 4A	*Eco*RI	P	10-20 kb	SAKAKI	*57763	E	485

[1] Digest — C = complete (limit), P = partial, S = random shear.
[2] Insert — c = cDNA, g = genomic.

† This material is cited in a U.S. and/or other Patent or application and may not be used to infringe the patent claims.

Human chromosome-specific libraries deposited in connection with the ATCC/NIH Repository are described in the ATCC/NIH Repository Catalogue of Human and Mouse DNA Probes and Libraries.

***The NIH requires the submission of a completed compliance agreement prior to shipment of any materials from the Repository. The form shown on page xi can be reproduced for this purpose.**